IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

MARIA LUISA GARZA and **OSCAR GARZA, SR.,**	§	
Plaintiffs,	§	
v.	§	**CIVIL ACTION NO. 2:12-CV-00198**
WYETH LLC, et al.,	§	
Defendants.	§	

ORDER DENYING GENERIC DEFENDANTS' SECOND MOTION TO DISMISS

Before the Court is Defendants Teva Pharmaceuticals USA, Inc.; Pliva, Inc.; Barr Pharmaceuticals, LLC; Barr Laboratories, Inc.; Watson Laboratories, Inc.; and Watson Pharma, Inc.'s Motion to Dismiss Plaintiffs' Fourth Amended Complaint. (D.E. 78.) The above-named Defendants manufactured the generic form of the drug Reglan/metoclopramide HCl (hereinafter referred to as "metoclopramide"), and these Defendant are collectively referred to herein as the "Generic Defendants." In a prior Order granting in part and denying in part Generic Defendants' first motion to dismiss, the Court dismissed Plaintiffs' failure-to-warn claims against Pliva, Inc., Barr Pharmaceuticals, LLC, and Barr Laboratories, Inc. (D.E. 84.) Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. remain in the suit. For the reasons set forth below, the present motion, Generic Defendants' second motion to dismiss, is DENIED.

FACTUAL ALLEGATIONS

The Court's analysis is based on the factual allegations set forth in Plaintiffs' Fourth Amended Complaint. (D.E. 72.) The relevant facts from the Fourth Amended Complaint, which

for purposes of this motion must be accepted as true and viewed in the light most favorable to Plaintiffs, are as follows.

This action is brought by Plaintiff Maria Luisa Garza and her husband, Plaintiff Oscar Garza, Sr. Mr. Garza seeks compensatory and exemplary damages for loss of consortium and household services as Ms. Garza's spouse. Ms. Garza seeks compensatory damages for mental anguish, physical disfigurement, physical impairment, loss of earnings, and reasonable and necessary medical expenses, in addition to exemplary damages.

Ms. Garza alleges her injuries resulted from being prescribed and ingesting the prescription drug metoclopramide over an extended period of time. Her physician first prescribed metoclopramide at a dosage of 10mg in June 2007 to treat gastroesophageal reflux disease. In July 2009, she began exhibiting abnormal muscle movements, which have since been linked to her overexposure to the drug. Prolonged exposure to metoclopramide is known to cause injuries to the central nervous system and the extrapyramidal motor system. Some patients develop tardive dyskinesia, a severe and often permanent neurological movement disorder.

Labeling approved by the United States Food and Drug Administration (FDA) for metoclopramide last appeared in the Physician's Desk Reference in 2002. In 2003, the FDA approved the addition of new warnings to be added to the drug's label. In July 2004, the FDA approved the addition of a bolded warning to the label stating that therapy with the drug "should not exceed 12 weeks in duration." And in February 2009, the FDA ordered a black box warning, its strongest, stating that "Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible . . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases."

During the time that Ms. Garza was prescribed and ingested metoclopramide, Generic Defendants were engaged in the business of testing, manufacturing, labeling, marketing, distributing, promoting, and/or selling either directly or indirectly, through third parties or related entities, metoclopramide in the State of Texas and in interstate commerce. Generic Defendants TEVA Pharmaceuticals USA, Inc. (TEVA), Watson Laboratories, Inc. (Watson Labs), and Watson Pharma, Inc. (Watson Pharma) failed to update their labels to match the 2003, 2004, and 2009 label changes approved by the FDA. As a result, Ms. Garza and her physicians were unaware of the risks and warnings about metoclopramide therapy exceeding twelve weeks. Had Ms. Garza and her physicians understood the nature and extent of the risk posed, her physicians would not have prescribed the medication past twelve weeks, and Ms. Garza would not have taken the drug past twelve weeks.

LEGAL STANDARD

On a Rule 12(b)(6) or 12(c) motion to dismiss, the Court must examine the complaint in the light most favorable to Plaintiffs, accepting all allegations as true and drawing all reasonable inferences in favor of Plaintiffs. *Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc.*, 677 F.2d 1045, 1050 (5th Cir. 1982); *Piotrowski v. City of Houston*, 51 F.3d 512, 514 (5th Cir. 1995). The Court need not, however, accept as true legal conclusions masquerading as factual allegations, and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Plaintiffs must allege sufficient facts that give rise to a reasonable inference that Defendants are liable. *Id.*; *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007). The factual allegations must raise Plaintiffs' claim for relief above the level of mere speculation. *Twombly*, 550 U.S. at 555. As long as the complaint, taken as a whole, gives rise to a plausible inference of

actionable conduct, Plaintiffs' claims should not be dismissed. *Id*. at 555–56. This test of the pleadings is devised to balance Plaintiffs' right to redress against the interests of the parties and the Court in minimizing expenditures of time, money, and resources. *Id*. at 557–58.

ANALYSIS

A. Texas Law

Generic Defendants argue that Plaintiffs' failure-to-update theory is not viable under Texas law. (D.E. 78 at 7.) As addressed in the Court's Order granting in part and denying in part Generic Defendants' first motion to dismiss, under Texas law, generic drug manufacturers have a duty to warn prescribing physicians of the dangers to patients associated with the use of their products of which the manufacturers had actual or constructive knowledge at the time the product was sold. (D.E. 84 at 5.) One way to satisfy this duty is for the generic drug manufacturers to provide warning labels with their drugs that are consistent with those approved by the FDA for the brand-name drug and utilized by the brand-name drug manufacturers. Furthermore, as discussed in this Court's previous Order, this duty to provide up-to-date labels warning about the known dangers of their drugs is not preempted under *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011) where the state law duty is consistent with the requirements set forth under federal drug laws. (See analysis set forth in D.E. 84 at 4–7.)

Generic Defendants now argue that Plaintiffs' failure-to-update theory of liability fails under Texas law because Plaintiffs claim that all labels were inadequate, at least through 2009, including labels containing the 2003 and 2004 FDA-approved updates to the brand-name labels. (D.E. 78 at 9–10.) The Fourth Amended Complaint, however, does not allege that the 2004 FDA-approved label was inadequate. Plaintiffs' assertion of liability is premised on allegations that long-term treatment beyond twelve weeks with metoclopramide increases a patient's risk of

developing certain central nervous system disorders such as tardive dyskenia, that Generic Defendants were aware of this risk, that changes were made to the brand-name drug labels in 2004 and 2009 that advised consumers and physicians of this risk, and that Generic Defendants failed to update their labels to warn consumers and their physicians of this risk.

The Court rejects Generic Defendants' argument that Plaintiffs' failure-to-update theory is not viable under Texas law. The Fourth Amended Complaint states a viable products liability claim under Texas law, which is not preempted by federal drug labeling laws under *Mensing*. Plaintiffs allege that Generic Defendants failed to update their labels about the danger of metoclopramide use exceeding twelve weeks, despite their actual or constructive knowledge of this risk, and despite FDA-approved labeling changes to the brand-name drug in 2004 and 2009 specifically warning of this risk. Viewing the allegations in the light most favorable to Plaintiffs, the Court concludes that Plaintiffs have alleged sufficient facts to give rise to a reasonable inference that Defendants are liable under Texas law.

B. Standing and Subject Matter Jurisdiction

Next, Generic Defendants argue that Plaintiffs lack standing and the Court lacks subject matter jurisdiction to consider Plaintiffs' failure-to-update theory of liability because there is no private right of action under the Food, Drug, and Cosmetic Act (FDCA). (D.E. 78 at 10–15.) Plaintiffs respond that the lack of a private cause of action under the FDCA is irrelevant because Plaintiffs' asserted cause of action arises under Texas' product liability laws, not federal law. (D.E. 85.)

Texas recognizes a cause of action for failure to provide an adequate product safety warning that results in an injury to a consumer. *See, e.g.*, *Centocor, Inc., v. Hamilton*, 372 S.W.3d 140 (Tex. 2012). Nowhere does the Fourth Amended Complaint assert a violation of the

FDCA. Moreover, the Court determined above that Plaintiffs have alleged sufficient facts to give rise to a reasonable inference that Defendants are liable under Texas' product liability laws. Accordingly, the Court concludes that Plaintiffs have standing to bring this cause of action and that the Court has subject matter jurisdiction to hear this case pursuant to 28 U.S.C. 1332.

C. Texas Civil Practice & Remedies Code § 82.007

Finally, Generic Defendants argue that Plaintiffs' claims are barred by TEX. CIV. PRAC. & REM. CODE § 82.007. (D.E. 78 at 19.) The Court considered this issue in its Order granting in part and denying in part Generic Defendants' first motion to dismiss. (D.E. 84 at 7–8.) Therein, the Court concluded that before a drug manufacturer may assert a presumption of no liability under Section 82.007, it must demonstrate that it distributed its product with the proper FDA-approved warnings and information. Plaintiffs theory of liability is that Generic Defendants failed to provide FDA-approved warnings and information. Therefore, viewing the allegations of the Fourth Amended Complaint in the light most favorable to Plaintiffs, Generic Defendants are not entitled to a presumption of no liability.

CONCLUSION

For the reasons set forth above, Generic Defendants' second motion to dismiss (D.E. 78) is DENIED. The Court retains Plaintiffs' failure-to-warn claims against Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc.

ORDERED this 28th day of June 2013.

Nelva Gonzales Ramos

NELVA GONZALES RAMOS
UNITED STATES DISTRICT JUDGE